GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:5259
ANSWERED ON:10.12.2010
APPROVAL TO DRUGS
Sukur Shri Jadhav Baliram;Thamaraiselvan Shri R.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the mechanism set up by the Government for the grant of licences for the import, manufacture and sale of drugs in the country;

(b) whether delay has been observed in issuance of such licences due to multiple authorities involved therein;

(c) if so, the details thereof indicating the average time taken for the purpose in the country;

(d) whether a number of applications for grant of approval of new drugs are pending with the concerned authority;

(e) if so, the details thereof alongwith the reasons therefor; and

(f) the time, by which these are likely to be cleared?

Answer

THE MINISTER OF HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) to (c) : The grant of license for import, manufacture and sale of drugs in the country is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and Rules 1945 made there under. The license for manufacturer and sale of drugs are granted by the licensing authorities appointed by the State Government under the said Act. No time frame has been provided under the said Act and Rules for grant of licenses, which governed/decided by the State Governments as per their requirements as per their requirements. The licenses for import of drugs are granted by the Central Drugs Standard Control Organisatio (CDSCO) headed by the Drugs Controller General (India) {DCG (I)} under the Central Government. The DCG(I) ensures that the import licenses are processed within specified timelines pursuant to satisfactory submission of the applications.

(d) to (f) Guidelines and requirements for approval for new drugs are specified in Drugs and Cosmetics Rules, 1945. The evaluation of new drug applications, wherein establishing safety and efficacy of the drug in is of paramount importance, is a complex process, which varies according to the nature of molecule/drug, the published data and information furnished by the applicants. It involves examination of chemical & pharmaceutical information, animal pharmacological & toxicological data, clinical data of safety & efficacy, laboratory test report etc. Various New Drug applications in the office of DCG (I) are under different stages of processing like under clinical trial, bio equivalence study, laboratory testing, examination of technical document etc. Different categories of applications are processed as per the specified timelines.